

Approval Date: January 14, 2005

FREEDOM OF INFORMATION SUMMARY

SUPPLEMENTAL NEW ANIMAL DRUG APPLICATION

NADA 038-233

RALGRO and RALGRO MAGNUM
(Zeranol)

This supplement provides for addition to the labeling of the statements “A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.” to the warning section and “Do not use in veal calves. Effectiveness and animal safety in veal calves have not been established.” immediately following the indications.

Sponsored by:

Schering-Plough Animal Health Corp.
1095 Morris Ave.
Union, NJ 07083

FREEDOM OF INFORMATION SUMMARY

RALGRO

Ear Implant for Beef Cattle and Feedlot Lambs

RALGRO MAGNUM

Ear Implant for Steers Fed in Confinement for Slaughter

1. GENERAL INFORMATION:

- a. File Number: NADA 038-233
- b. Sponsor: Schering-Plough Animal Health Corp.
1095 Morris Ave.
Union, NJ 07083
Drug Labeler Code: 000061
- c. Established Name: Zeranol
- d. Propriety Names: RALGRO
RALGRO MAGNUM
- e. Dosage Form: Implantation (ear implant) as per 21 CFR 522.2680
- f. How Supplied: RALGRO (beef cattle): Each carton contains 20 1-cartridge boxes with each cartridge containing 24 doses (36 mg per dose). Also supplied in a carton with 10 24-dose cartridges (36 mg dose). Also supplied in a carton with 10 10-dose strip cartridges (36 mg dose).
- RALGRO (feedlot lambs): Each carton contains 10 24-dose cartridges (12 mg dose).
- RALGRO MAGNUM: Each carton contains 10 10-dose strip cartridges (72 mg dose).
- g. How Dispensed: OTC
- h. Amount of Active Ingredients: RALGRO (beef cattle): 36 mg zeranol.
- RALGRO (feedlot lambs): 12 mg zeranol.
- RALGRO MAGNUM: 72 mg zeranol.

- i. Route of Administration: Subcutaneous implantation on the posterior aspect of the middle one-third of the ear by means of an implant gun.
- j. Species/Class: RALGRO: Beef cattle and feedlot lambs.
RALGRO MAGNUM: Steers fed in confinement for slaughter.
- k. Recommended Dosage: RALGRO:
Beef cattle: One implant containing 36 mg zeranol.
Feedlot lambs: One implant containing 12 mg zeranol.
RALGRO MAGNUM: One implant containing 72 mg zeranol.
- l. Pharmacological Category: Steroid hormone.
- m. Indications: RALGRO (beef cattle): For increased rate of weight gain and improved feed conversion of weaned beef calves, growing beef cattle, feedlot steers and feedlot heifers. For increased rate of weight gain in suckling beef calves.
RALGRO (feedlot lambs): For increased rate of weight gain and improved feed conversion of growing lambs.
RALGRO MAGNUM: For increased rate of weight gain and improved feed efficiency steers fed in confinement for slaughter.
- n. Effect of Supplement: This supplement provides for addition to the labeling of the statements "A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal." to the warning section and "Do not use in veal calves. Effectiveness and animal safety in veal calves have not been established." immediately following the label indications.

2. *DRUG EFFECTIVENESS:*

No new effectiveness data are required for the approval of this supplement. The products' effectiveness has been established in the Freedom of Information (FOI) Summaries for the parent new animal drug application for RALGRO and RALGRO MAGNUM (NADA 038233).

3. *TARGET ANIMAL SAFETY:*

No new target animal safety data are required for the approval of this supplement. The products' target animal safety has been established in the Freedom of Information (FOI) Summaries for the parent new animal drug application for RALGRO and RALGRO MAGNUM and (NADA 038233).

4. *HUMAN SAFETY:*

No new human food safety data are required for the approval of this supplement. The products' human food safety has been established in the Freedom of Information (FOI) Summaries for the parent new animal drug application for RALGRO and RALGRO MAGNUM (NADA 038233).

5. *AGENCY CONCLUSIONS:*

The information submitted in support of this NADA satisfies the requirements of section 512 of the Federal Food, Drug, and Cosmetic Act and 21 CFR Part 514 of the implementing regulations providing for the addition to the labeling of the statements "A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal." to the warning section and "Do not use in veal calves. Effectiveness and animal safety in veal calves have not been established." immediately following the indications. The labeling is modified to conform to agency policy (69 FR 135 pages 42443-42444 dated July 15, 2004, and 69 FR 68 page 18594 dated April 8, 2004.)

The Center for Veterinary Medicine has concluded that, for these products, adequate directions for use by the layperson have been provided and the products will have over-the-counter (OTC) status. Label directions are accompanied by pictorial diagrams and detailed instruction in plain language. The drugs are not controlled substances. The products' status remains OTC. The labeling is adequate for the intended use and has sufficient warnings/statements to prevent illegal use in veal calves.

This approval does not qualify for marketing exclusivity under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act.

Under the Center's supplemental approval policy (21 CFR 514.106(b)(2)), this is a Category II change. The approval of this change is not expected to have any adverse effect on the safety or effectiveness of this new animal drug. Accordingly, this approval did not require a reevaluation of the safety and effectiveness data in the parent application.

No patent information was submitted by the sponsor with this application.

6. ATTACHMENTS:

Facsimile Labeling is attached as indicated below:

RALGRO (beef cattle) 20 24-Dose Single Cartridge Box Carton Label (RALOGUN)
RALGRO (beef cattle) Package Insert (RALOGUN)
RALGRO (beef cattle) 10 24-Dose Cartridge Carton Label (RALOGUN)
RALGRO (beef cattle) 1 24-Dose Cartridge Box Label (RALOGUN)
RALGRO (beef cattle) 10 10-Dose Strip Cartridge Carton Label (DUR-A-TRACT Injector)
RALGRO (beef cattle) 10-Dose Strip Cartridge Package Insert (DUR-A-TRACT Injector)
RALGRO (feedlot lambs) 10 24-Dose Cartridge Carton Label (RALOGUN)
RALGRO (feedlot lambs) Package Insert (RALOGUN)
RALGRO MAGNUM 10 10-Dose Strip Cartridge Carton Label (DUR-A-TRACT Injector)
RALGRO MAGNUM 10-Dose Strip Cartridge Package Insert (DUR-A-TRACT Injector)